K012230

OCT - 9 2001

510(k) SUMMARY
pHEM-ALERT
September 30, 2001

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in this 510(k) premarket notification was in accordance with 21 CFR 807.87.

1. Sponsor/Submitter

Sponsor
FemTek, LLC
50 Bellefontaine Street
Pasadena, CA 91105-3181
Attention: James C. Caillouette, M.D., President
Telephone: 626-796-7148
Facsimile: 626-793-1651

Submitted by:
Consultant
Joel S. Faden, Ph.D., Inc.
11605 Hitching Post Lane
Rockville, MD 20852
Contact person: Joel Faden
Telephone: 301-881-9139
Facsimile: 301-881-9249

2. Name of Device

Trade Name: pHEM-ALERT
Common/Usual Name: pH paper
Classification Name: "Obstetric pH Paper", 85LNW, unclassified

3. Legally Marketed Predicate Devices

pHEM-ALERT 510(k) K960648

4. Indications for Use / Intended Use

The indications and intended uses for the pHEM-ALERT device are:

"The pHEM-ALERT® test measures vaginal pH (acidity) and is intended for use by women who have any of the following vaginal symptoms:

- Itching
- Burning
- Unpleasant odor

- Unusual discharge

This test may help decide if these symptoms are caused by an infection that may require follow-up by your healthcare provider. This test is only intended for women who have normal menstrual periods (periodic vaginal bleeding). This device is not validated for use in pregnant women."

5. Device Description

The pHEM-ALERT provides a method for the lay user to measure her vaginal pH. The pHEM-ALERT test is comprised of a plastic probe with pH paper on one end, a color chart and a package insert. The plastic probe is in the shape of small flat key. pHEM-ALERT is indicated for measuring vaginal pH for the purpose of differentiating normal and abnormal conditions in symptomatic women. The device is inserted into the vagina and the measurement taken.

6. Substantial Equivalence

This version of the pHEM-ALERT is identical to the currently available version, except for the package insert, which has been modified to specifically address the needs of the lay user.

Two clinical studies were designed and carried in support of the Substantial Equivalency. The studies were designed to address the requirements, of appropriate guidelines. In particular, the clinical studies were performed to demonstrate that the lay user could read and understand the labeling and record accurate results The pHEM-ALERT and its labeling were found to be well designed, readable and understandable. The pHEM-ALERT was not affected by anticipated variation in user technique. The pHEM-ALERT demonstrated reasonable test performance.

In conclusion, these data demonstrated that the test performance characteristics of this version of the pHEM-ALERT are reasonable and acceptable and that this version of the pHEM-ALERT is substantially equivalent to the original version.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FemTek, LLC
c/o Joel S. Faden, Ph.D.
President/CEO
11605 Hitching Post Lane
Rockville, MD 20852

OCT - 9 2001

Re: k012230
Trade/Device Name: pHEM-ALERT
Regulation Number: 21 CFR 862.1550
Regulation Name: Urinary pH (nonquantitative) test system
Regulatory Class: Class I, reserved
Product Code: LNW
Dated: July 15, 2001
Received: July 16, 2001

Dear Dr. Faden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Device Name: pHEM-ALERT

Indications For Use:

The indications and intended uses for the OTC version of the pHEM-ALERT device are:

"The pHEM-ALERT® test measures vaginal pH (acidity) and is intended for use by women who have any of the following vaginal symptoms:

- Itching
- Burning
- Unpleasant odor
- Unusual discharge

This test may help decide if these symptoms are caused by an infection that may require follow-up by your healthcare provider. This test is only intended for women who have normal menstrual periods (periodic vaginal bleeding). This device is not validated for use in pregnant women."

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012230

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: OR Over-The-Counter: ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)